

## **REMARKS**

### **Objection to the Title**

Applicants have amended the title to be more descriptive of the claimed invention. The title has been amended to **COMPOSITION AND METHOD FOR REDUCING DIARRHEA IN A MAMMAL**.

### **Claim Amendments**

Claims 1 and 4-14 are amended in this Amendment A. No new matter has been added. Claim 1 is amended to more particularly define the composition of the invention by specifying amounts of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids in the composition. Claims 4-14 are amended to simply rephrase the claims, remove redundancies or unnecessary terms, or correct grammatical or obvious errors. Applicants submit that such amendments do not affect the scope of the claims, and are permissible under MPEP §2163.07.

Upon entry of this amendment, claims 1-14 will remain pending in the application. Applicants reserve the right to pursue any canceled subject matter and/or any other subject matter disclosed in this application in one or more later-filed divisional and/or continuation applications.

### **Rejection Under 35 U.S.C. § 112**

Claims 1 and 4-13 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants request withdrawal of this rejection.

#### *Claim 1*

Claim 1 is rejected because the term “anti-diarrhea effective amount” is unclear. Applicants have amended claim 1 to more particularly describe the composition and to overcome the rejection by replacing the term “anti-diarrhea effective amount” with minimum concentrations of the required ingredients. Reconsideration and withdrawal of the rejection in view of the amendments to claim 1 is respectfully requested.

*Claims 4-13*

Claims 4-13 are rejected for use of the notation “wt%.” Applicants have amended the claims to replace the notation with the phrase “percent by weight.” Reconsideration and withdrawal of the rejection with respect to claims 4-13 is respectfully requested.

**Rejections Under 35 USC § 102**

*1. Shields, Jr. et al.*

Claims 1-3, 5, 7 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Shields, Jr. et al. (U.S. Patent No. 6,156,355). Applicants request withdrawal of this rejection.

The present invention is directed to methods and compositions useful in ameliorating diarrhea caused by GI tract inflammation in a mammal. For example, as defined by amended claim 1, the present invention is directed to a composition suitable for oral ingestion by a mammal having GI tract inflammation wherein the composition comprises at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s).

Shields, Jr. et al. discuss breed-specific dog food formulations comprising chicken meat as the major ingredient. The formulations are described as being “designed taking into account the different food allergies of different dog breeds.” See Col. 3, lines 30-41. Although the reference discusses a “combination of ingredients to help maintain gastrointestinal function,” nothing in the reference describes a composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) as required by amended claim 1. Because the cited reference does not teach every limitation of the present invention, Applicants respectfully submit that amended claim 1 is patentable over Shields, Jr. et al., U.S. Patent No. 6,156,355. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is requested.

Claims 2-3, 5 and 7, which depend in whole or in part from claim 1, are submitted to be patentable over Shields, Jr. et al. for the same reasons as set forth above with respect to claim 1. Further, independent claim 14 has been amended to incorporate the limitations of amended claim

1. Accordingly, independent claim 14 is also submitted to be patentable over Shields, Jr. et al. for the same reasons as set forth above with respect to claim 1.

2. *Chandler*

Claims 1-3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler (In Practice, 2002). Applicants respectfully request withdrawal of this rejection

The Chandler article discusses various dietary modifications which may be beneficial in the management of gastrointestinal disease in dogs and cats. Although the reference generally discusses glutamine as a potential energy source in stressed animals and other dietary modifications including an increase in fiber and an increase in omega-3 fatty acids, nothing in the reference teaches a composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) as required by amended claim 1. Because the cited reference does not describe each and every limitation of the present invention, Applicants respectfully submit that amended claim 1 is patentable over Chandler (In Practice, 2002). Reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is requested.

Claims 2 and 3, which depend in whole or in part from claim 1, are submitted to be patentable over Chandler for the same reasons as set forth above with respect to claim 1. Further, independent claim 14 has been amended to incorporate the limitations of amended claim 1. Accordingly, independent claim 14 is also submitted to be patentable over Chandler for the same reasons as set forth above with respect to claim 1.

**Rejections Under 35 USC § 103**

1. *Shields, Jr. et al. in view of Wadsworth et al. and Klimberg et al.*

Claims 1-14 are rejected under 35 U.S.C. 103(a) as obvious over Shields, Jr. et al. (U.S. Patent No. 6,156,355) in view of Wadsworth et al. (US 2002/082276 A1) and Klimberg et al. (Arch. Surg., 1990). The rejection is traversed for the reasons set forth below.

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of

ordinary skill in the art, to combine the teachings of prior art references; and the references, when combined, must teach all of the claim limitations. See MPEP 2143. As described above, the present invention is directed to methods and compositions useful in ameliorating diarrhea caused by GI tract inflammation in a mammal. In particular, the embodiment defined in amended claim 1 is directed to a composition suitable for oral ingestion by a mammal having GI tract inflammation wherein the composition comprises at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s). As further described below, nothing in the cited references remotely teaches or suggests a composition for oral ingestion by a mammal having GI tract inflammation wherein the composition comprises at least about 0.1% by weight glutamine and at least about 0.1% by weight omega-3 fatty acid(s). Thus, Applicants submit that the cited references do not provide the necessary motivation or suggestion to combine the reference teachings; and, even if combined, the references do not teach all of the claim limitations of the present invention.

The principal reference, Shields, Jr. et al., discusses breed-specific dog food formulations comprising chicken meat as the major ingredient. Although the reference discusses a “combination of ingredients to help maintain gastrointestinal function” as described above, nothing in the reference teaches or suggests ameliorating diarrhea in a mammal having GI tract inflammation. Further, the reference is entirely devoid of any teaching regarding a formulation having at least about 0.1% by weight glutamine and at least about 0.1% by weight omega-3 fatty acids. In particular, Shields et al. discuss a single formulation, the “herding diet,” which includes microbial cultures, bromelain (a pineapple extract) and glutamine in addition to the combination of ingredients described above for protection of the GI tract in breeds that suffer from gastrointestinal immune deficiency. See, Col 11, lines 59 – Col. 12, line 17. Nothing in the reference remotely teaches or suggests any amount of glutamine or omega-3 fatty acids which may ameliorate diarrhea in a mammal having GI tract inflammation. Therefore, Applicants respectfully submit that the composition defined in amended claim 1, which requires at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) is

patentable over the cited reference Shields, Jr. et al. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Applicants respectfully submit that the deficiencies of the principal reference are not overcome by resorting to the teachings of Wadsworth et al. or Klimberg et al. Wadsworth et al. discusses animal food formulations containing *Morinda Citrifolia* extract. Although glutamine is listed as a component of a formulation under the title of providing improved digestive system support, nothing in the reference remotely teaches or suggests the importance of glutamine in the composition or whether anything in the composition provides any beneficial effect with respect to alleviating diarrhea in a patient suffering from GI tract inflammation. Further, Wadsworth et al. do not describe glutamine in any formulation comprising fermentable fiber, antioxidants or omega-3 fatty acids as required by instant claim 1. Accordingly, it is respectfully submitted that the cited reference does not provide the necessary teaching or motivation for one skilled in the art to adapt the teachings of Shields, Jr. et al. to arrive at the present invention.

Klimberg et al. discuss the administration of glutamine to protect intestinal mucosa from radiation-induced ulceration. In particular, glutamine is discussed for its healing effects in patients undergoing whole abdominal radiation. Nothing in the reference remotely teaches or suggests a composition comprising glutamine in combination with fermentable fiber, antioxidants or omega-3 fatty acids as required by instant claim 1. Accordingly, it is respectfully submitted that the cited reference does not provide the necessary teaching or motivation for one skilled in the art to adapt the teachings of Shields, Jr. et al. to arrive at the present invention.

Because the cited references, either alone or in combination, do not adequately teach or suggest any composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s), Applicants submit that the Examiner has failed to establish a *prima facie* case of obvious such that claim 1 is patentable over Shields, Jr. et al. (U.S. Patent No. 6,156,355) in view of Wadsworth et al. (US 2002/082276 A1) or Klimberg et al. (Arch. Surg. 1990). Reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a) is requested.

Claims 2-13, which depend in whole or in part from claim 1, are submitted to be patentable over the cited references for the same reasons as set forth above with respect to claim

1. Further, independent claim 14 has been amended to incorporate the limitations of amended claim 1. Accordingly, independent claim 14 is also submitted to be patentable over the cited references for the same reasons as set forth above with respect to claim 1.

2. *Chandler*

Claims 1-14 are rejected under 35 U.S.C. 103(a) as obvious over Chandler (In Practice, 2002). As described above, Chandler generally discusses dietary modifications which may be useful in treating gastrointestinal disorders in dogs and cats. The reference is distinguishable from the present invention in that Chandler does not provide any particular teaching with respect to amounts or combinations of dietary modifications which may be suitable for any particular conditions. Thus, it is submitted that the reference does not provide any of the necessary teaching or motivation to lead one skilled in the art to prepare a composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) as required by amended claim 1. Accordingly, Applicants submit that amended claim 1 is patentable over Chandler (In Practice 2002). Reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a) is requested.

Claims 2-13, which depend in whole or in part from claim 1, are submitted to be patentable over Chandler for the same reasons as set forth above with respect to claim 1. Further, independent claim 14 has been amended to incorporate the limitations of amended claim 1. Accordingly, independent claim 14 is also submitted to be patentable over Chandler for the same reasons as set forth above with respect to claim 1.

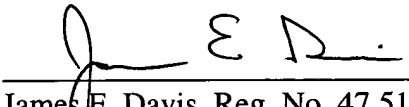
**Conclusion**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot by this amendment. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314) 446-7683.

Amendment A  
Serial No. 10/729,450  
February 22, 2005

Applicants have enclosed a check in the amount of \$120.00 for the purchase of a one-month extension of time under 37 C.F.R. 1.136(a). If any other fees are owed with this response, the Commissioner is hereby authorized to charge such fees to Deposit Account No. **08-0750**. In addition, if there is ever a deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **08-0750**.

Respectfully submitted,



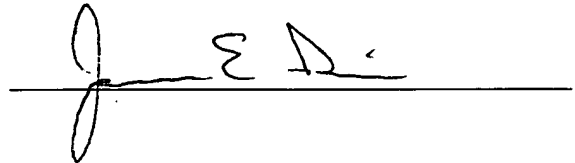
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Amendment A  
Serial No. 10/729,450  
February 22, 2005

**CERTIFICATE OF MAILING UNDER 37 CFR § 1.8**

I certify that this correspondence is being deposited with the U.S. Postal Service on **February 22, 2005** with sufficient postage as first class mail (including Express Mail per MPEP §512), and addressed to **Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.**

A handwritten signature in black ink, appearing to be "J E D", is written over a horizontal line.

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